K063008
p 1/2

Xperex Inc..
510(k) Submission
Health Check Kiosk
510(k) Summary
September 22, 2006

JUN - 7 2007

(1) Submitter Information

Name: Xperex Inc.

Address:

384 Oyster Point Blvd
South San Francisco, CA 94080

Telephone Number: 650-266-2013

Contact Person:

Dr. George Myers
Medsys Inc.
377 Route 17 S
Hasbrouck Heights, NJ 07604
Telephone 201-727-1703
Fax 201-727-1708

Date Prepared: September 22, 2006

(2) Name of Device

Trade Name: Health Check Kiosk
Common Name: Kiosk for Measurement of Health Parameters
Classification name: System, measurement, blood-pressure, non-invasive

(3) Equivalent legally-marketed devices.

1. Lifeclinic Inernational, K040562
2. Advanced Monitoring Caregiving, K051544
3. Remote Nurse, K041308

(4) Description

The Health Check Kiosk is a kiosk that is erected in public spaces, and provides a location where the general public can measure various health parameters. The Health Check kiosks are intended only to provide information, and are not for diagnostic use. No charge is made for use of the kiosk, but advertising may be

›sted inside of it. It is planned to locate the kiosk in non-medical settings such as gyms, corporate offices and retail stores.

(5) Intended Use

The Health Check Kiosk is intended to be a multi-functional unit that provides tests for the general public to measure personal health parameters such as weight, body fat, blood pressure and pulse rate in public places and/or corporate environments.

(6) Performance Data

(a) Non-clinical tests

Health Check Kiosk has been extensively validated by itself and in conjunction with the associated measurement devices.

(b) Clinical tests

Clinical tests are not necessary, since the Health Check Kiosk uses the same technology as the predicate devices.

.) Conclusions

The Health Check Kiosk is equivalent in safety and efficacy to the legally-marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 7 2007

Xperex Corporation
c/o Medsys Inc.
George Myers
377 Route 17 S
Hasbrouck Heights, NJ 07604

Re: K063008
Trade/Device Name: Health Check Kiosk
Regulation Number: 21 CFR 870.1130
Regulation Name: Non-Invasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: May 18, 2007
Received: May 21, 2007

Dear Mr. Myers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

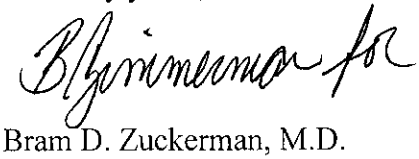
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at 240-276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K063008

Device Name: Health Check Kiosk

Indications for Use:

The Health Check Kiosk is indicated for use by the general public so that a user can measure his/her own health parameters using devices cleared for use by the public. It is not a diagnostic device, and only furnishes data so that users can consult their personal physicians.

Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K063008